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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/975,020 | 10/12/2001 | Alan J. Magill | P66822US0 (WRAIR 98-40/46 | 7596 |

7590 08/26/2003

Office of the Staff Judge Advocate
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-JA (Ms. Elizabeth Arwine)
504 Scott Street
Fort Detrick, MD 21702-5012

| EXAMINER |
|---|
| SHAHNAN SHAH, KHATOL S |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | 7 |

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/975,020 | MAGILL ET AL. | |
| | Examiner | Art Unit | |
| | Khatol S Shahnan-Shah | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *4,11,12,18,22-25,29 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,11,12,18,22-25,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

**1.** Applicants' amendment A, received June 19, 2003, paper # 6 is acknowledged. Claims 1-3, 5-10,13-17, 19-21 and 26-28 were canceled. New claims 29-30 were added.

### *Election/Restrictions*

**2.** Applicants' election without traverse of June 19, 2003, paper # 6 is acknowledged. Applicants elected group II, claims 4, 11, 12, 18 and 22-25, which are drawn to a product (i.e. a microfluidized lysate from Leishmania parasite). Applicants have added new claims 29 and 30, which are also directed, to the elected invention of group II. Applicants have elected species Leishmania *mexicana* from claims 12 and 30 and pharmaceutical composition of claim 25.

**3.** Currently claims 4, 11, 12, 18, 22-25 and 29-30 are pending and under consideration.

### *Information Disclosure Statement*

**4.** The information disclosure statement filed 9/25/2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Applicants, statement that copies of references 1, 2 and AA-AR are enclosed with the IDS is noted. However, the examiner cannot locate those copies. If applicants wish that those reference to be considered, the applicants need to submit other copies of those references. The examiner feels bad if this causes any inconvenience on part of the applicants.

### *Claim Rejections - 35 USC § 112*

**5.** The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**6.** Claims 18 and 22- 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition, does not reasonably provide enablement for a vaccine or a pharmaceutical composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to identify or make the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP) 2164.01(a). Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples (6) the quantity of experimentation, (7) the relative skill of those in the art, and (8) the breadth of the claims.

When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated base on that limitation. See in re Vaeck, 947 F. 2d 488, 495,20 USPQ 2d 1438, 1444 (Fed Cir, 1991).

Dorland's Medical Dictionary (29th Edition, 2000) defines "vaccine" as "a suspension of attenuated or killed microorganisms (bacteria, viruses, or rickettsiae), or of antigenic proteins derived from them, administered for the prevention, amelioration, or treatment of infectious diseases. In the instant case the applicants' invention is not enabled for the prevention, amelioration, or treatment of infectious diseases. And one skilled in the art will not be able to make/and or use the invention without undue experimentation.

In the instant case claim 18 is drawn to a vaccine. There are no examples or testing of a vaccine are mentioned in the specification. There are no results or data provided that shows vaccination of individuals was performed. The examples in the specification pages 12-18, examples 1-4 mentioning the production of a microfluidized lysate and skin test antigen assay. No other information is provided in regard to a vaccine or its protective immunity.

Steadman's Medical Dictionary (26th Edition, 1995) defines "pharmaceutical" as "relating to pharmacy or to pharmaceutics"; "pharmacy" as "the practice of preparing and dispensing drugs", and "drug" as "Therapeutic agent; any substance, other than food, used in the prevention, diagnosis, alleviation, treatment, or cure of disease".

While the definition of "pharmaceutical" is broad, but it is not so broad to cover any use of a substance on or in the body of a subject, only those uses intend to prevent, diagnose, alleviate treat, or cure a disease within the animal to which the substance was administered.

Claims 22-25 are drawn to a "pharmaceutical" composition. M.P.E.P. § 2164.01 (c), paragraph 3 recites:

In the instant application regarding claims 22-25 to the pharmaceutical composition, there is no working example or data given in the specification. The instant specification does not teach how to use the composition, without undue experimentation, for the prevention, diagnosis, alleviation, treatment, or cure of a disease in the animal to which the substance is administered.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

**8.** Claims 4, 11, 12, 18, 22-25, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites " microfluidizing a slurry of at least one Leishmania parasite through a chamber". It is not clear what applicants intend in reciting "at least one Leishmania". Does it mean that just one single parasite or a single strain of said parasite?

***Claim Rejections - 35 USC § 102***

**9.** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**10.** Claims 4, 11, 12, 18, 22-25 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Leishmania Research project DoD-8B (copy attached) or Stitler et al. (Production of Leishmania Skin Antigen Test GMP Protocol requirements 1 and 2, 1994 and 1995). Claims are drawn to a microfluidized lysate preparation from a least one Leishmania parasite.

Leishmania Research project DoD-8B and Stitler et al teach a microfluidized lysate preparation from Leishmania parasite manufactured in May 1995 (see attached papers specially abstract #300, page 186, 44$^{th}$ Annual Meeting of American Society of Tropical Medicine and Hygiene). The prior art teaches the claimed product. Limitations such as use of the product in kits or pharmaceutical composition will be inherent in the teachings of Leishmania Research project DoD-8B.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

***Conclusion***

**11.** No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

August 13, 2003

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER